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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/686,970

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Rudolf Pachl

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EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

07/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/686,970	Applicant(s) PACHL ET AL.	
	Examiner LORE RAMILLANO	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/1/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 21-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19, 21-31 and 38 is/are allowed.
- 6) ☒ Claim(s) 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/16/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. In applicant's reply filed on 4/1/08, applicant amended claim 32. Claims 19 and 21-38 are pending and under examination.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 10/18/02. It is noted, however, that applicant has not filed a certified copy of the German 10248555.0 application as required by 35 U.S.C. 119(b).
3. The Office regrettably regrets indicating in the Office Action Summary (PTOL-326), filed on 12/3/07, that all of the certified copies of the priority documents have been received. The box indicating that "none of" the certified documents have been received should have been marked instead.

Response to Amendment

Allowable Subject Matter

4. Claims 23-31 are allowed. The reasons for allowance are stated in the prior Office action (filed on 6/4/07).
5. In addition, claims 19, 21-22, and 38 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record (Moorman) fails to teach or fairly suggest a method of operating an analyte evaluation in instrument that comprises the following steps: operating an optical measuring device to determine the amount of the sample placed on

the test element; correcting the analyte content of the sample if the amount of the sample placed on the test element is determined to be less than a predetermined calibration value; and assessing the amount of the sample placed on the test element, in combination with the remaining features and elements of the claimed invention.

Prior art rejections

6. The rejection of claim 21 by Moorman; and the rejection of claims 19, 22, and 38 over Moorman in view of Yamamoto. The rejections of claims 32-37 over the prior art are maintained.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 32 and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Moorman (US 5356782).

Moorman teaches a method comprising: a test field (10); a reagent in the test field (i.e. regions I, II, and III), wherein (i) the interaction between the reagent and the analyte causes a first photometrically detectable signal and (ii) the first photometrically detectable signal is a function of concentration of the analyte in the sample (i.e. column 8, lines 31-43); and a control substance in the test field, wherein (i) the interaction between the control substance and the sample matrix causes a second photometrically detectable signal and (ii) the second photometrically detectable signal is a function of

the amount of the sample applied to the test field (i.e. column 8, lines 3-30). Moorman's signals are photometrically detectable because he teaches in column 17, lines 57-62, for example, that the interactions disclosed above were observed by fluorescence under long wave UV light.

Furthermore, Moorman teaches that the latter interaction stated above is a function of the amount of sample applied to the test field because he teaches in column 14, lines 47 to column 15, line 14, for example, that the test strips can be prepared to perform "concentration assay," which is an assay to determine whether an analyte of interest is present in excess of insufficiency in a sample.

9. **Claims 32, 33, and 35** are rejected under 35 U.S.C. 102(b) as being anticipated by Fleming et al. ("Fleming," US 6365417).

In figures 1-7, Fleming teaches a method comprising: a test field (i.e. 80 and 86); a reagent (i.e. capture agents) in the test field, wherein (i) the interaction between the reagent and the analyte causes a first photometrically detectable signal and (ii) the first photometrically detectable signal is a function of concentration of the analyte in the sample; and a control substance (i.e. fluorescein, 102, column 7, lines 7-8) in the test field, wherein (i) the interaction between the control substance and the sample matrix (i.e. saliva or other oral secretions collected) causes a second photometrically detectable signal and (ii) the second photometrically detectable signal is a function of the amount of the sample applied to the test field (i.e. column 6, line 64 to column 7, line 8; column 9, line 35 to column 10, line 10). Fleming's signals are photometrically detectable because he teaches in column 6, line 64 to column 7, line 8, for example,

that the interactions disclosed above were observed by visual, spectroscopic, photochemical, biochemical, immunochemical, electrical, optical or chemical means.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. **Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Carr et al. ("Carr," WO 01/25171 A1).

The teachings of Moorman are stated above. Moorman does not specifically teach having a control substance comprising a chromophore. Carr teaches utilizing a chromophore because it enables quantitation of the products of a synthesis to be carried out. Carr further teaches that such quantitation can be absolute quantitation or relative quantitation, or both. (i.e. p. 7, lines 23-30). It would have been obvious to a person of ordinary skill in the art to incorporate a chromophore into Moorman's invention because a chromophore has a very strong absorption at a unique or characteristic wavelength, which is usually distinct from the wavelengths at which the maximum absorbances of a typical substrate molecule might be found. (i.e. p. 7, lines 23-30).

12. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Caspers et al. ("Caspers," US 4081672).

The teachings of Moorman are stated above. Moorman does not specifically teach having a control substance comprising a fluorescein. Caspers teaches utilizing sodium fluorescein dye because it has the advantage that fluorescence may be detected in solution concentrations as small as 1×10^{-7} mole concentrations where at

about 5200A the extinction coefficient is roughly 0.01cm^{-1} . (i.e. column 3, lines 9-15). It would have been obvious to a person of ordinary skill in the art to modify Moorman by incorporating a fluorescein dye as a control substance since the amount of analyte that is collected in each sample is in minute amounts and incorporating a fluorescein dye would enable that analyte to be detectable.

13. **Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Mach et al. ("Mach," US 5723308).

The teachings of Moorman are stated above. Moorman does not specifically teach having a control substance comprising chlorophenol red. Mach teaches the benefit of using a large excess of chlorophenol red is the bright red color of chlorophenol red in contrast with the other colors in a solution allows easier and faster detection of the specimen (i.e. column 5, lines 38-50). It would have been obvious to a person of ordinary skill in the art to modify Moorman by incorporating chlorophenol red as the control substance because it would be desirable to use a control substance that produces a distinguishable color when it interacts with the sample to make it easier for the analyst to quickly determine the signal produced by the control substance.

14. **Claim 37** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Mach, as applied to claim 36 above, and further in view of applicant's admitted prior art on page 15 of the specification.

The teachings of Moorman and Mach are stated above. Moorman in view of Mach does not specifically teach having a reagent comprising phosphomolybdic acid. However, applicant teaches that the use of 2, 18 phosphomolybdic acid in the detection

of glucose is known in the art. It would have been obvious to a person of ordinary skill in the art to modify the modified Moorman by incorporating phosphomolybdic acid as a reagent for glucose because it would be desirable to utilize a reagent that is easily available and well-known to be used for such detection.

Response to Arguments

15. Applicant's arguments, see p. 9 and 13 filed 4/1/08, with respect to claims 19, 21-22, and 38 have been fully considered and are persuasive. The rejections with regard to these claims have been withdrawn.

16. Applicant's arguments filed 4/1/08, with respect to claims 32-37, have been fully considered but they are not persuasive.

35 USC 102(b) rejection by Moorman

In response to applicant's argument, with regard to claims 32 and 33, that Moorman fails to teach or suggest the inclusion of a second component that interacts with the sample, examiner disagrees. Arguments that the alleged anticipatory prior art is "teaches away from the invention" or "suggests," or "equivalent," are not germane to a rejection under section 102. However, examiner will interpret that applicant's arguments on p. 9 are referring to the 35 USC 102(b) rejection. Moorman does disclose the structural limitations recited in claims 32 and 33. As indicated above, Moorman discloses a test field (i.e. fig. 1, 10); a reagent in the test field (i.e. col. 8, lines 1-2; and a control substance (i.e. col. 8, lines 3-30). Moorman further discloses a device capable of producing photometrically detectable signals since Moorman discloses in example 2, for instance, that the interactions on the test strip were observed by fluorescence under

UV light. The language recited after the terms, i.e. "for," "capable," "causes," "when," doesn't add to the patentability of these apparatus-types of claims since such language recited after these terms appear to recite what the device does rather than structurally defining the claimed invention.

In response to applicant's argument, with regard to claims 32 and 33, that Moorman fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., two separate and distinct reagents) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, claims 32 and 33 recite a singular reagent and not a plurality of reagents.

35 USC 102(b) rejection by Fleming

In response to applicant's argument that Fleming only discloses fluorescein as a label, and not as a control substance for determining that volume of sample added to the device, examiner does not find this applicant convincing. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As stated above, the language recited after the terms, i.e. "for," "capable," "causes," "when," doesn't add to the patentability of these apparatus-type of claims since such language recited after these terms appear to recite what the device does rather than structurally defining the claimed invention. Here, as

stated above and in the prior Office action (filed on 12/3/07), it appears that Fleming discloses the structural limitations recited in claims 32, 33, and 35. Because Fleming's device discloses such structural limitations and appears to be capable of performing such functional limitations, Fleming reads on claims 32, 33, and 35.

In response to applicant's argument that Fleming fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., two separate reagents) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, claims 32 and 33 recite a singular reagent and not a plurality of reagents. In claim 32, applicant recites having "a reagent." In claim 33, applicant further recites having "the reagent," which expressly indicates that applicant is referring to the same reagent. Thus, claims 32, 33, and 35 do not appear to recite two separate reagents.

In response to applicant's argument that Fleming's adequacy indicator dye is not the equivalent of applicant's control agent, examiner disagrees. As stated in the prior rejection (filed on 12/3/07), the control substance (i.e. fluorescein, 102, column 7, lines 7-8) in the test field is capable of interacting with a sample matrix (i.e. saliva or other oral secretions collected) to cause a photometric signal because the labels (i.e. fluorescein) utilized by Fleming are capable of producing a signal observed by visual, spectroscopic, photochemical, biochemical, immunochemical, electrical, optical or chemical means (i.e. column 6, line 64 to column 7, line 8).

35 USC 103(a) rejection over Moorman in view of Carr

In response to applicant's argument that Carr is devoid of any suggestion that a chromophore could be used to quantitate the total amount of liquid that is placed on a test element, examiner does not find this argument convincing. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, Moorman, as stated above, reads on the structural limitations recited in claim 32. Carr discloses a chromophore. The combination of Moorman and Carr is proper because it would have been obvious to a person of ordinary skill in the art to incorporate a chromophore into Moorman's invention because a chromophore has a very strong absorption at a unique or characteristic wavelength, which is usually distinct from the wavelengths at which the maximum absorbances of a typical substrate molecule might be found. (Carr, i.e. p. 7, lines 23-30). Because examiner has provided sufficient motivation to combine the references, the rejection is proper.

35 USC 103(a) rejection over Moorman in view of Caspers

In response to applicant's argument that Caspers's fluorescein dye solution fails to suggest that it could be used as a control substance to determine the amount of sample that is placed in contact with the control substance, examiner does not find this argument convincing. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, Moorman, as stated above, reads on the

structural limitations recited in claim 32. Casper discloses a sodium fluorescein dye. The combination of Moorman and Casper is proper because it would have been obvious to a person of ordinary skill in the art to modify Moorman by incorporating a fluorescein dye as a control substance since the amount of analyte that is collected in each sample is in minute amounts and incorporating a fluorescein dye would enable that analyte to be detectable. Because examiner has provided sufficient motivation to combine the references, the rejection is proper.

35 USC 103(a) rejection over Moorman in view of Mach

In response to applicant's argument that Mach's is devoid of any suggestion that phosphomolybdic acid could be used to quantitate the amount (volume) of liquid that is placed on a test element, examiner does not find this argument convincing. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, Moorman, as stated above, reads on the structural limitations recited in claim 32. Casper discloses that the benefit of using a large excess of chlorophenol red is the bright red color of chlorophenol red in contrast with the other colors in a solution because it allows easier and faster detection of the specimen. The combination of Moorman and Mach is proper because it would have been obvious to a person of ordinary skill in the art to modify Moorman by incorporating chlorophenol red as the control substance because it would be desirable to use a control substance that produces a distinguishable color when it interacts with the sample to make it easier for

the analyst to quickly determine the signal produced by the control substance. Because examiner has provided sufficient motivation to combine the references, the rejection is proper.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Lore Ramillano
Examiner
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